

TOPPIK MENS HAIR REGROWTH TREATMENT EXTRA STRENGTH- minoxidil solution
Spencer Forrest, Inc.

Toppik Men's Hair Regrowth Treatment
Extra Strength

Drug Facts

Active ingredient

Minoxidil 5% w/v

Purpose

Hair regrowth treatment for men

Use

to regrow hair on the scalp (vertex only, see picture inside of package)

Warnings

For external use only. For use by men only.

Flammable: Keep away from fire or flame.

Do not use if:

- You are a woman
- Your amount of hair loss is different than that shown on the inside of this insert or your hair loss is on the front of the scalp. Minoxidil Topical Solution, 5% is not intended for frontal baldness or receding hairline
- You have no family history of hair loss
- Your hair loss is sudden and/or patchy
- You do not know the reason for your hair loss
- You are under 18 years of age. Do not use on babies and children
- Your scalp is red, inflamed, irritated or painful
- You use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product:

- Do not apply on other parts of the body
- Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water
- Some people have experienced changes in hair color and/or texture
- It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
- The amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask a doctor if:

- Side effects occur: You may report side effects to FDA at 1-800-FDA-1088 or to Toppik Inc. at 1-800-THICKEN (844-2536).
- Chest pain, rapid heartbeat, faintness, or dizziness occurs

- Sudden, unexplained weight gain occurs
- Your hands or feet swell
- Scalp irritation or redness occurs
- Unwanted facial hair growth occurs
- You do not see hair regrowth in 4 months

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply one mL with sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area
- Using more or more often will not improve results
- Continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

Other information

- See hair loss pictures on inside of this package.
- Before use, read all information on package and enclosed leaflet.
- Keep the package. It contains important information.
- Hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with
- In clinical studies of mostly white men aged 18-45 years with moderate degrees of hair loss, Minoxidil Topical Solution, 5% extra strength for men provided more hair regrowth than Minoxidil Topical Solution, 2%.
- Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

Inactive ingredients

Alcohol 30%, Propylene Glycol 50% v/v, Purified Water

Questions or comments?

Call your health professional or Toppik Inc. at 1-800-THICKEN (844-2536)

DIST. BY:

TOPPIK INC.

11777 San Vicente Blvd, Suite 650

Los Angeles, CA 90049

Toppik

Hair Regrowth Treatment

MEN'S

EXTRA STRENGTH

5% Minoxidil Topical Solution

Unscented

Save this leaflet for future reference.

- Provides more hair regrowth than Minoxidil Topical Solution, 2%.
- It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results. Please read this leaflet carefully. It will help you understand how to use Toppik Men's Hair Regrowth Treatment and what to expect from its use. If you have any questions after reading this leaflet, or anytime while

using Toppik Men's Hair Regrowth Treatment, you should ask your health care professional or call us at **1-800-THICKEN (844-2536)**. You can also contact us via email at support@toppik.com or on our website at TOPPIK.com.

What is Toppik Men's Hair Regrowth Treatment Extra Strength?

Toppik Men's Hair Regrowth Treatment is a colorless liquid medication containing 5% minoxidil for use only on the scalp to help regrow hair in men.

Who may use Toppik Men's Hair Regrowth Treatment Extra Strength?

Toppik Men's Hair Regrowth Treatment Extra Strength is for use only by men. Toppik Men's Hair Regrowth Treatment Extra Strength may be appropriate for you if you are a male at least 18 years old and experiencing gradually thinning hair or gradual hair loss on the top of the scalp (vertex only, as shown on the illustration below).



It is not intended for frontal baldness or a receding hairline. The common inherited thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss. Toppik Men's Hair Regrowth Treatment Extra Strength is for men with hair loss or thinning hair that begins on the vertex of the scalp. Toppik Men's Hair Regrowth Treatment Extra Strength is more likely to regrow hair in men with hair loss in the range shown in the diagram. If men have more hair loss than shown, Toppik Men's Hair Regrowth Treatment Extra Strength may not work. Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. If you have no family history of gradual thinning hair or of gradual hair loss, or your hair loss is patchy, see your doctor.

Who should NOT use Toppik Men's Hair Regrowth Treatment Extra Strength?

- Women should not use Toppik Men's Hair Regrowth Treatment Extra Strength because studies have shown it works no better in women than Women's 2% Minoxidil Topical Solution. Some women may also grow facial hair. In addition, Toppik Men's Hair Regrowth Treatment Extra Strength may be harmful if used during pregnancy or breast-feeding.
- Toppik Men's Hair Regrowth Treatment Extra Strength should not be used on babies or for children under 18 years old.
- Toppik Men's Hair Regrowth Treatment Extra Strength will not prevent or improve hair loss which may occur with the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; too much vitamin A intake), low thyroid states (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Toppik Men's Hair Regrowth Treatment Extra Strength will not improve hair loss due to:
- Damage from the use of hair care products which cause scarring or deep burns of the scalp.
- Hair grooming methods such as cornrowing or ponytails which require pulling the hair tightly back from the scalp.

Do not use if you are not sure of the reason for your hair loss.

Toppik Men's Hair Regrowth Treatment Extra Strength differs from Minoxidil Topical Solution, 2% (Regular Strength) for Women products in the following ways:

- Contains 5% minoxidil (regular strength contains 2%)
- Regrows more hair

- With Toppik Men's Hair Regrowth Treatment Extra Strength results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results.
- Is more likely to cause skin irritation. If scalp irritation continues or worsens, stop use and see a doctor. See Warnings on package or bottle label.

Will Toppik Men's Hair Regrowth Treatment Extra Strength work for me?

The amount of hair regrowth is different for each person. Not everyone will respond to Toppik Men's Hair Regrowth Treatment Extra Strength. The response to Toppik Men's Hair Regrowth Treatment Extra Strength cannot be predicted. It is unlikely anyone will be able to grow back all their hair. However, to see your best results with Toppik Men's Hair Regrowth Treatment Extra Strength, make sure you get the medicine directly to the scalp and apply it twice a day, every day. You may get better results if you have been losing your hair for a short period of time or have little hair loss. However, for some men Toppik Men's Hair Regrowth Treatment Extra Strength may not work.

How soon can I expect results from using Toppik Men's Hair Regrowth Treatment Extra Strength?

Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Toppik Men's Hair Regrowth Treatment Extra Strength also takes time. Results may be seen as early as 2 months with twice daily use. For some men, it may take at least 4 months for results to be seen. If you do not see any results after 4 months, stop using Toppik Men's Hair Regrowth Treatment Extra Strength. When you first begin to use Toppik Men's Hair Regrowth Treatment Extra Strength, your hair loss may increase temporarily for up to 2 weeks. This is likely a sign that you are getting rid of old hairs in order to regrow more new hairs. This temporary increase in hair loss is expected and is a part of the process for how Toppik Men's Hair Regrowth Treatment Extra Strength regrows hair. Remember, this increased hair loss is temporary. However, if it continues after two weeks, see your doctor.

If Toppik Men's Hair Regrowth Treatment Extra Strength is working, what will the hair look like?

At first, hair growth is usually soft, downy, colorless hairs (like peach fuzz). After further use, the new hairs should be the same color and thickness as the other hairs on your scalp.

How long do I need to use Toppik Men's Hair Regrowth Treatment Extra Strength?

If you experience hair regrowth, continued use of Toppik Men's Hair Regrowth Treatment Extra Strength is necessary or the hair loss will begin again. In studies with Minoxidil Topical Solution 5% (Extra Strength), hair regrowth has not been shown to last longer than 48 weeks of continuous treatment in large clinical trials.

What happens if I completely stop using Toppik Men's Hair Regrowth Treatment Extra Strength? Will I keep the new hair?

Continuous use of Toppik Men's Hair Regrowth Treatment Extra Strength is needed to maintain hair regrowth. If you stop using Toppik Men's Hair Regrowth Treatment Extra Strength, you will lose your newly regrown hair in 3 to 4 months.

How do I use Toppik Men's Hair Regrowth Treatment Extra Strength?

For best results, apply 1 mL (6 sprays) 2 times a day directly onto the scalp in the hair loss area. Using more or more often will not improve results. Each bottle should last one month, if used as directed. It is not necessary to use fingertips when applying Toppik Men's Hair Regrowth Treatment. However, if you do use your fingertips, wash your hands well immediately afterwards. Allow time for Toppik Men's Hair Regrowth Treatment Extra Strength to dry completely before wearing a hat, or lying on a pillow, etc. Toppik Men's Hair Regrowth Treatment Extra Strength may cause staining of clothing or linens if damp on the scalp. When applying Toppik Men's Hair Regrowth Treatment Extra Strength at night, be sure to allow 2 to 4 hours to dry completely. Never take this product by mouth or apply to

other parts of the body.

When do I use Toppik Men's Hair Regrowth Treatment Extra Strength?

Apply Toppik Men's Hair Regrowth Treatment Extra Strength once in the morning and once at night. The nighttime application should occur 2 to 4 hours before going to bed to allow for drying. Each bottle should last one month, if used as directed.

What if I miss a dose or forget to use Toppik Men's Hair Regrowth Treatment Extra Strength?

If you miss one or two daily doses of Toppik Men's Hair Regrowth Treatment Extra Strength, just continue with your next dose. You should not make up for missed doses.

Can I use Toppik Men's Hair Regrowth Treatment Extra Strength more than twice a day? Will it work faster, better?

No. Toppik Men's Hair Regrowth Treatment Extra Strength will not work faster or better if used more than two times a day. Studies have been carefully conducted to determine the correct amount of Toppik Men's Hair Regrowth Treatment Extra Strength needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

What kind of shampoo should I use with Toppik Men's Hair Regrowth Treatment Extra Strength?

If you wash your scalp before applying Toppik Men's Hair Regrowth Treatment Extra Strength, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.?

Yes. Hair sprays, spritzes, or styling aids may be used on your hair while using Toppik Men's Hair Regrowth Treatment Extra Strength. For best results, Toppik Men's Hair Regrowth Treatment Extra Strength should be allowed to soak into the scalp before using any styling products. Try to develop a good routine of applying Toppik Men's Hair Regrowth Treatment Extra Strength first, and then applying styling products and style as usual. Keep in mind that your best results will be seen with proper application.

Can I have my hair colored or permed or use hair relaxers while using Men's Toppik Men's Hair Regrowth Treatment Extra Strength?

Yes. We have no evidence that coloring or perming your hair or that the use of relaxers change the effect of Toppik Men's Hair Regrowth Treatment Extra Strength. However, because the use of a permanent wave and hair color can cause scalp irritation on certain people, we recommend the following precautions:

1. To avoid possible scalp irritation, you should make sure all of the Toppik Men's Hair Regrowth Treatment Extra Strength has been washed off the hair and scalp before using color or perm chemicals.
2. For best results, do not apply Toppik Men's Hair Regrowth Treatment Extra Strength on the same day that you use a chemical treatment on your hair.
3. Do not use Toppik Men's Hair Regrowth Treatment Extra Strength for 24 hours after using any chemicals to make sure your scalp has not been irritated by the perm or color treatment. If no irritation occurs, continue use of Toppik Men's Hair Regrowth Treatment Extra Strength as usual.

Simply restart your normal Toppik Men's Hair Regrowth Treatment Extra Strength routine. There is no need to use more Toppik Men's Hair Regrowth Treatment Extra Strength to make up for missed applications. Missing 1 day of Toppik Men's Hair Regrowth Treatment Extra Strength will not affect your hair regrowth results.

Can I apply Toppik Men's Hair Regrowth Treatment Extra Strength and wash my hair an hour later?

No. For Toppik Men's Hair Regrowth Treatment Extra Strength to work best, you should allow it to stay on the scalp for about 4 hours before washing.



Using the Sprayer Applicator

Important: When applying Toppik Men's Hair Regrowth Treatment, make sure the medicine comes in direct contact with the scalp. The medicine will not work if it is sprayed only on your hair and does not reach your scalp.

Carefully follow the instructions below to use the child-resistant sprayer pump to apply Toppik Men's Hair Regrowth Treatment Extra Strength

1. Remove the bottle of Toppik Men's Hair Regrowth Treatment Extra Strength from the package.
2. Firmly hold the bottle upright with the turning wheel on the back of the bottle facing you. Push in the small tab located to the bottom right of the turning wheel.
3. While holding the tab in, press down on the top of the sprayer and turn the upper part of the sprayer with the turning wheel to the left until the spray nozzle is centered between the beveled grooves on the front of the bottle.
4. Then prime the sprayer by holding the bottle upright and pumping the sprayer 5 times to ensure delivery of a full spray. Be careful not to inhale the mist.
5. Aim the sprayer at your area of thinning hair or hair loss and pump the sprayer 6 times to apply a 1 mL dose twice a day.
6. After applying Toppik Men's Hair Regrowth Treatment Extra Strength, use the turning wheel to turn the sprayer cap back to the right to release the tab which places the sprayer nozzle behind the sprayer cap wall. Make sure the sprayer cannot be pushed or pumped before putting the bottle away.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

What are the most common side effects with Toppik Men's Hair Regrowth Treatment Extra Strength?

The most common side effects are itching and skin irritation of the treated area of the scalp. If scalp irritation continues, stop use and see a doctor. Toppik Men's Hair Regrowth Treatment Extra Strength contains alcohol, which will cause burning or irritation of the eyes. If Toppik Men's Hair Regrowth Treatment Extra Strength accidentally gets into eyes, rinse with large amounts of cool tap water.

If Side Effects Occur: You may report side effects to FDA at 1-800-FDA-1088 or call us at **1-800-THICKEN (844-2536)**. You can also contact us via email at support@toppik.com or on our website at **TOPPIK.com**.

Can Toppik Men's Hair Regrowth Treatment Extra Strength produce unwanted hair growth?

Unwanted hair growth on the face and other parts of the body has been reported in women. But it is rare and reversible. If you develop unwanted hair, stop using Toppik Men's Hair Regrowth Treatment Extra

Strength. Over time, the unwanted hair, if caused by Toppik Men's Hair Regrowth Treatment Extra Strength, will go away. You can take the following steps to decrease the chances of unwanted hair growth:

1. Limit the application of Toppik Men's Hair Regrowth Treatment Extra Strength only to the scalp;
2. If you use your hands to apply Toppik Men's Hair Regrowth Treatment Extra Strength, wash your hands well immediately afterwards; and
3. After your nighttime application of Toppik Men's Hair Regrowth Treatment Extra Strength, allow enough drying time before going to bed (usually 2 to 4 hours).

Can I use Men's Toppik Men's Hair Regrowth Treatment Extra Strength for baldness or hair loss in babies or children?

No. Toppik Men's Hair Regrowth Treatment Extra Strength must not be used to treat baldness or hair loss in babies and children.

If you have any other questions, ask your health care professional or call us at **1-800-THICKEN (844-2536)**. You can also contact us via email at **support@toppik.com** or on our website at **TOPPIK.com**.

PRINCIPAL DISPLAY PANEL - 60 mL Bottle Canister Label

NDC# 61355-570-60

MEN'S

Clinically proven to help regrow hair. Reactivates hair follicles to stimulate regrowth.

Toppik

Hair Regrowth Treatment
5% MINOXIDIL TOPICAL SOLUTION
EXTRA STRENGTH

Easy-To-Use
Spray
Unscented

Not For Use By Women

TOPPIK INC.

60mL (2 fl oz) Bottle/30-Day Supply



NDC# 61355-570-60

548167

MEN'S

Clinically proven to help regrow hair. Reactivates hair follicles to stimulate regrowth.

TOPPIK

Hair Regrowth Treatment
5% MINOXIDIL TOPICAL SOLUTION
EXTRA STRENGTH



Easy-To-Use
Spray
Unscented

Not For Use By Women

TOPPIK INC.
60mL (2 fl oz) Bottle/30-Day Supply

Drug Facts

Active ingredient

Minoxidil 5% w/v.....Hair regrowth treatment for men

Purpose

Use to regrow hair on the scalp (vertex only; see picture inside of package)

Warnings

For external use only. For use by men only.

Flammable: Keep away from fire or flame.

Do not use if: • You are a woman • Your amount of hair loss is different than that shown on the inside of this insert or your hair loss is on the front of the scalp. Minoxidil Topical Solution, 5% is not intended for frontal baldness or receding hairline • You have no family history of hair loss • Your hair loss is sudden and/or patchy • You do not know the reason for your hair loss • You are under 18 years of age. Do not use on babies and children • Your scalp is red, inflamed, irritated or painful • You use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product: • Do not apply on other parts of the body • Avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water • Some people have experienced changes in hair color and/or texture • It takes time to regrow hair. Results may occur at 2 months with twice a day usage. For some men, you may need to use this product for at least 4 months before you see results. • The amount of hair regrowth is different for each person. This product will not work for all men.

Stop use and ask a doctor if: • Side effects occur: You may report side effects to FDA at 1-800-FDA-1088 or to Toppik Inc. at 1-800-THICKEN (844-2536). • Chest pain, rapid heartbeat, faintness, or dizziness occurs • Sudden, unexplained weight gain occurs • Your hands or feet swell



• Scalp irritation or redness occurs • Unwanted facial hair growth occurs • You do not see hair regrowth in 4 months

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions: • Apply one mL with sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area • Using more or more often will not improve results • Continued use is necessary to increase and keep your hair regrowth, or hair loss will begin again

Other information • See hair loss pictures on inside of this package. • Before use, read all information on package and enclosed leaflet. • Keep the package. It contains important information. • Hair regrowth has not been shown to last longer than 48 weeks in large clinical trials with continuous treatment with • In clinical studies of mostly white men aged 18-45 years with moderate degrees of hair loss, Minoxidil Topical Solution, 5% extra strength for men provided more hair regrowth than Minoxidil Topical Solution, 2%. • Store at controlled room temperature 20° to 25°C (68° to 77°F). Keep tightly closed.

DRUG FACTS CONT'D INSIDE

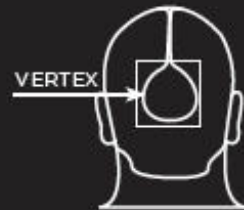


Toppik Men's Hair Regrowth Treatment Extra Strength (Minoxidil Topical Solution, 5%) is for men who have general thinning of hair on the top of the scalp (vertex only, as shown below). Not intended for frontal baldness or a receding hairline. Toppik Men's Hair Regrowth Treatment Extra Strength (Minoxidil Topical Solution, 5%) has been shown to regrow hair in men with the following degrees of thinning hair or hair loss:



This Package Contains:





- One 60mL (2 fl oz) Spray Bottle of Toppik Men's Hair Regrowth Treatment Extra Strength (one month supply)

- Information leaflet with complete directions on how to use and obtain best results

(Read enclosed leaflet before use)

If men have more hair loss or hair loss in a place different than shown above, Toppik Men's Hair Regrowth Treatment Extra Strength may not work.

Drug Facts Cont'd

Inactive Ingredients

Alcohol 30%, Propylene Glycol 50% w/w, Purified Water

Questions or comments?

Call your health professional or Toppik Inc. at
1-800-THICKEN (844-2536)

Store at USP Controlled Room Temperature
20° to 25° C (68° to 77° F)

DIST. BY:
TOPPIK INC.
11777 San Vicente Blvd, Suite 650
Los Angeles, CA 90049
Made in USA
TOPPIK.com 1-800-THICKEN (844-2536)

23-MN05

minoxidil solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61355-570
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Minoxidil (UNII: 5965120SH1) (Minoxidil - UNII:5965120SH1)	Minoxidil	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61355-570-60	1 in 1 CANISTER		
1		60 mL in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076239	01/01/2014	

Labeler - Spencer Forrest, Inc. (191988237)

Revised: 5/2014

Spencer Forrest, Inc.